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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,146	05/24/2002	Philip Braithwaite	2245/108	9521
2101	7590	07/02/2004	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			PATEL, MITAL B	
			ART UNIT	PAPER NUMBER
			3743	9
DATE MAILED: 07/02/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/070,146

Applicant(s)

BRAITHWAITE, PHILIP

Examiner

Mital B. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 4, 21, 23-25 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-8, 18-20, 26-30 and 32 is/are rejected.
- 7) ☒ Claim(s) 9-17 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/23/02
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-3, 5-19, 20, 22, 26-30, and 32, drawn to a delivery device with a radial actuator and a method of delivering a material using the delivery device, classified in class 206, subclass 533.
  - II. Claims 4-18, 21-33, drawn to a delivery device with a plurality of magazines, classified in class 221, subclass 69.
  - III. Claims 24, 25, and 31, drawn to a magazine comprising spools, classified in class 221, subclass 119.
2. The inventions listed as Groups I, II, and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the independent claims in the groupings lack some feature that should be common between all of the independent claims, i.e., any independent claim should contain all essential features which features are also novel. Independent claim 1 of Group I lacks a plurality of magazines and spools. Independent claim 4 of Group II lacks spools. Independent claim 21 of Group III lacks a plurality of magazines. Independent claim 24 of Group III lacks a metering member.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as weekly pill dispenser that would require only one magazine for the week, rather than a plurality of magazines. See MPEP § 806.05(d).

4. Inventions I and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as a device for delivering/dispersing candy. See MPEP § 806.05(d).

5. Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention III has separate utility such as weekly pill dispenser that would require only one magazine for the week, rather than a plurality of magazines. See MPEP § 806.05(d).

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and the search required for Groups I, II, and III is different for each group, restriction for examination purposes as indicated is proper.

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8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. During a telephone conversation with Mr. Asher on 3/19/04 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-3, 5-19, 20, 22, 26-30, and 32. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4, 21-25, and 31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Please note that claims 5-12 depend from either claim 1 or claim 4; claim 4 is not elected but since claims 5-12 in the alternative depend on claim 1, and Applicant elected claims 5-12, they are considered on the merits and grouped with Group I for examination.

### ***Drawings***

10. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference character(s) mentioned in the description: Reference characters 112 and 120. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required

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corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

11. It should be noted that the abstract of the disclosure submitted as the front page of WO document has been received from papers submitted from the International Bureau and outlined in MPEP 1893.03 (e).

12. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. **Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:**

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.

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- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

### ***Claim Objections***

13. Claim 1 is objected to because of the following informalities: The term "rotatable" should read --rotatable--. Appropriate correction is required.

14. There is a lack of antecedent basis for the following limitations:

- Claim 18, lines 13-14, "the **medicament** delivery device"
- Claim 19, line 16, "the inhaler"

Correction is required.

### ***Claim Rejections - 35 USC § 112***

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

17. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

***Claim Rejections - 35 USC § 102***

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 1, 2, 5, 6, 7, 18, 19, 26, 27, 29, and 32 as best understood is rejected under 35 U.S.C. 102(b) as being anticipated by Kirk et al (US 4,860,740).

20. **As to claims 1 and 32**, Kirk et al teaches a delivery device **10** comprising a rotatable metering member **11** adapted to dispense a measured amount of material (**See Col. 5, lines 33-43**), a material delivery passage **18** and a material delivery orifice **19**, and at least one actuator member **36** adapted to move the metering member **11** from a material retaining position to a material dispensing position (**See Col.6, lines 50-58**) characterized in that the actuator member **36** moves in a substantially radial direction and actuates the metering member **11** in a substantially radial direction.

21. **As to claim 2**, Kirk et al teaches a delivery device characterized in that the device comprises a plurality of metering members **11** (**See Fig. 1**) adapted to dispense a measured amount of material, said metering members being held in a rotatable magazine **20**.



22. **As to claim 5**, Kirk et al teaches a delivery device characterized in that the material is a medicament (**See Col. 5, line 43**).

23. **As to claim 6**, Kirk et al teaches a delivery device characterized in that the material is a dry powder (**See Col. 5, line 43**).

24. **As to claim 7**, Kirk et al teaches a delivery device characterized in that the magazine **20** is substantially circular (**See Col. 6, lines 27-33**).

25. **As to claim 18**, Kirk et al teaches a delivery device characterized in that the medicament deliver device is an inhaler (**See Col. 5, lines 33-34**).

26. **As to claim 19**, Kirk et al teaches a delivery device characterized in that the inhaler is a dry powder inhaler (**See Col. 5, lines 33-34**).

27. **As to claim 26**, Kirk et al teaches a method of delivering a material which comprises using a delivery device according to claim 1 (**See Col. 7, lines 39-65**).

28. **As to claim 27**, Kirk et al teaches a method of administering a dry powder medicament using a delivery device according to claim 6 (**See Col. 7, lines 39-65**).

29. **As to claim 29**, Kirk et al teaches a method of treatment of a patient with a respiratory disorder comprising the administration of a therapeutically effective amount of medicament using an inhaler according to claim 18 (**See Col. 2, lines 28-35**).

30. Claims 1, 6, 27, 28, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Newell et al (US 5,035,237).

31. **As to claims 1**, Newell et al teaches a delivery device comprising a rotatable metering member **3** adapted to dispense a measured amount of material **5**, a material delivery passage **27** and a material delivery orifice (**opening at end of 27**), and at least

one actuator member **60** adapted to move the metering member **3** from a material retaining position to a material dispensing position (**See Col.6, lines 50-58**) characterized in that the actuator member **60** moves in a substantially radial direction and actuates the metering member **3** in a substantially radial direction.

32. **As to claim 6**, Newell et al teaches a delivery device characterized in that the material is a dry powder (**See Col. 2, lines 3-5**).

33. **As to claim 27**, Newell et al teaches a method of administering a dry powder medicament using a delivery device according to claim 6 (**See Col. 2, lines 3-5**).

34. **As to claim 28**, Newell et al teaches a method characterized in that a combination of medicaments are administered (**See Col. 2, lines 47-58**).

35. **As to claim 30**, Newell et al teaches the use of salmeterol (**please note in Col. 2, lines 34-58 where Newell cites as examples a few asthma medications; it is known that salmeterol is an asthma medication and although Newell does not fully list all asthma medications, the Examiner believes that salmeterol is covered in the disclosure of the device suitable for use with asthma medications**) in the manufacture of an inhaler according to claim 1.

36. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Minshull et al (WO 92/03175).

37. **As to claim 20**, Minshull et al teaches a dry powder inhaler comprising a metering member **C** adapted to dispense a measured amount of medicament, an inhalation passage (**formed by opening at end of 48**) and a mouthpiece **48**, and at least one push rod **54,56** adapted to move the metering member **C** from a medicament

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retaining position to a medicament dispensing position characterized in that the push rod **54,56** moves in essentially substantially radial direction (**note the push rod moves in the same radial plane as on which magazine 4 rotates**) and actuates the metering member in a substantially radial direction.

38. Claims 1, 2, 3, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Tucker (5,485,939).

39. **As to claim 1**, Tucker teaches a delivery device **12** comprising a rotatable metering member **14** adapted to dispense a measured amount of material **16**, a material delivery passage **60** and a material delivery orifice **48**, and at least one actuator member **76** adapted to move the metering member **14** from a material retaining position to a material dispensing position characterized in that the actuator member **76** moves in a substantially radial direction and actuates the metering member **14** in a substantially radial direction.

40. **As to claim 2**, Tucker teaches a delivery device characterized in that the device comprises a plurality of metering members **14** (**See Fig. 2**) adapted to dispense a measured amount of material **16**, said metering members being held in a rotatable magazine **24**.

41. **As to claim 3**, Tucker teaches a delivery device characterized in that the device is adapted to take a plurality of magazines **24** (**See Figs.1-3**).

42. **As to claim 8**, Tucker teaches a delivery device characterized in that the device comprises a pair of magazines **24** (**See Figs. 1-3**).

***Allowable Subject Matter***

43. Claims 9-17 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

44. The following is a statement of reasons for the indication of allowable subject matter: As to claim 9, the prior art of record does not teach nor render obvious the overall claimed combination of a delivery device provided with means for engaging a first magazine whilst disengaging a second magazine and which engaging means is moveable from an engaging to a disengaging position and vice-versa. It should be noted that claim 9 sets forth means plus function language which means is set forth in the specification to include male and female interlocking members, in which case the magazine is provided with the female member and a drive means is provided with the male member having a drive plate, the male member further comprising a resilient protrusion to engage with a female member of the first magazine. It should be noted the closest prior art of record is to Tucker (US 5,484,939) in which a pair of magazines in a deliver device are disclosed. However, in Tucker electronic circuitry is used to engage a first magazine while disengaging a second magazine. As to claim 15, the prior art of record does not teach nor render obvious the overall claimed combination of a delivery device in that the medicament metering member comprises a spool and spool carrier wherein the void between the spool carrier is filled with medicament.


**Conclusion**

45. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6601729, 6328034, US 6325241, US 6273085, US 6116238, US 6065472, US 6006747, US 5921237, US 5450160, US 5799821, US 5775536, US 5664697, US 5562231, US 5551597, US 5622166, US 5409132, US 5253782, US 5207217, US 5152422, US 4627432, US 4047635, and US 3876269.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Mital B. Patel  
Examiner  
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